

**REMARKS**

Claims 26-67 are pending. The Examiner withdrew claims 51-67 from consideration. Claims 26-50 are under consideration.

**I. Applicants Statement of Interview Summary**

The undersigned thanks Examiner Tung for the courtesy of the telephone conference on November 3, 2006. The rejection of claims 26, 28-35, 39-40, 43-45, and 47-50 under 35 U.S.C. § 102(e) as allegedly being anticipated by Wittwer et al., U.S. Patent No. 6,174,670 ("Wittwer") was discussed. The rejections of claims 27, 36-38, 41, 42, and 46 under 35 U.S.C. § 103(a) over Wittwer, in view of U.S. Patent No. 6,103,465 ("Johnston-Dow") and/or U.S. Patent No. 6,790,945 ("Lukhtanov") were also discussed.

Specifically, the undersigned pointed out that independent claim 26 recites multiple elements. The undersigned also pointed out that, in the previous response filed at the U.S. Patent and Trademark Office on June 22, 2006 ("previous response"), Applicants argued that Wittwer does not teach or suggest, either expressly or inherently, each and every element of independent claim 26. Specifically, the undersigned stated that in the previous response, Applicants argued that Wittwer does not teach or suggest at least the claim language "determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition . . . ," according to the method of claim 26. The undersigned also pointed out that in the present Action, the Examiner did not address that argument in any of the § 102(e) or § 103(a) rejections.

During the interview, the Examiner acknowledged that she had not considered the claim language “determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition . . . ,” according to the method of claim 26, in view of Wittwer, nor in view of Wittwer, Johnston-Dow, and/or Lukthanov. The Examiner stated that she would consider that claim language and each of Applicants’ arguments concerning that language, which were presented in the previous response. The Examiner also stated that, if she asserts a rejection with new art, she would remove the finality of the rejection.

Below, Applicants respond to the rejections in the present Action. In responding to those rejections, Applicants reiterate the arguments presented in the previous response. No new arguments are presented.

**II. Rejection of Claims 26, 28-35, 39, 40, 43-45, and 47-50 Under 35 U.S.C. § 102(e)**

The Examiner maintained the rejection of claims 26, 28-35, 39, 40, 43-45, and 47-50 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,174,670 (“Wittwer”). Action at page 2, item no. 1. Applicants respectfully traverse that rejection.

The Examiner alleged that “Wittwer et al. disclose the method of monitoring hybridization during polymerase chain reaction using of double stranded DNA dye or specific hybridization probes and quantitating amplified DNA. . . .” Action at page 2.

The Examiner acknowledged that

Wittwer et al. do not explicitly disclose combining nucleic acid from the sample with at least one set of reaction composition comprising a first

reaction composition and second reaction composition, both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide.

*Id.* at page 3. But the Examiner alleged that

Wittwer et al. disclose that three fluorescence-monitoring techniques for PCR are performed. Each reaction composition has a pair of primers and fluorescence indicator (See column 32, lines 28-61). It is inherent in this teaching that the nucleic acid sample combined at least one set of reaction compositions comprising a first reaction composition and second reaction composition, both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide.

*Id.*

The Examiner stated that

[t]he response argues that the Examiner failed to address the language when discussing Wittwer regarding the limitations 'combining nucleic acid from the sample with at least one set of reaction composition comprising a first reaction composition and second reaction composition, both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide' which is not explicitly taught by Wittwer.

*Id.* at pages 3-4.

As discussed in the Applicants Statement of Interview Summary above, in the previous response, Applicants actually addressed the claim language "determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition. . . ." Since the Examiner

agreed to consider Applicants' argument presented in the previous response, that argument is reiterated below for the convenience of the Examiner.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 at 2100-73 (8th ed. rev. 3, August 2005) (citing *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Wittwer does not expressly describe, either expressly or inherently, each and every element of independent claim 26.

For example, Wittwer does not teach or suggest "determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition . . . ," according to the method of claim 26. In fact, the Examiner failed to address that language when discussing Wittwer.

Thus, the Examiner has failed to establish that Wittwer teaches or suggests, either expressly or inherently, each and every element of independent claim 26. Claims 28-35, 39, 40, 43-45, and 47-50 ultimately depend from claim 26, and thus, also comprise "determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition. . . ." Accordingly, for at least that reason, claims 26, 28-35, 39, 40, 43-45, and 47-50 are not anticipated by Wittwer. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 26, 28-35, 39, 40, 43-45, and 47-50 under 35 U.S.C. § 102(e).

Because Wittwer fails to anticipate claims 26, 28-35, 39, 40, 43-45, and 47-50 under § 102(e), Applicants do not need to address the Examiner's contentions concerning other elements of those claims. By not addressing those contentions, Applicants in no way acquiesce to those contentions.

**III. Rejection of Claims 27, 36-38, 41, and 42 Under 35 U.S.C. § 103(a)**

The Examiner maintained the rejection of claims 27, 36-38, 41, and 42 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wittwer, as applied to claims 26, 28-35, 39, 40, 43-45, and 47-50, and further in view of U.S. Patent No. 6,103,465 ("Johnston-Dow"). Action at page 4, item no. 2. Applicants respectfully traverse that rejection.

The Examiner acknowledged that "Wittwer et al do not disclose a nucleic acid sequencing reaction on the amplification product, the source of DNA sample used as listed in claims 36-38 and determining at least one HLA type." *Id.* The Examiner alleged that "Johnston-Dow et al. disclose a method for typing HLA class I gene and the method involving DNA sequencing techniques. . . ." *Id.* The Examiner further alleged that "Johnston-Dow et al. also disclose that any source of human nucleic acid can be used [, and that] Johnston-Dow et al. further indicate that HLA typing is performed routinely in connection with many medical indications. . . ." *Id.* at pages 4-5. The Examiner also alleged that "it would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to apply the sequencing method of Johnston-Dow et al. because the method of Johnston-Dow et al. is applied to the locus-specific nucleic acid amplification followed by sequence-specific detection of the

amplified product for the DNA typing of HLA class I gene via DNA sequencing. . . .” *Id.*  
at page 5.

The Examiner stated that

[t]he response argues that as discussed above in connection with claim 26, Wittwer would not have taught or suggested the limitation ‘combining nucleic acid from the sample with at least one set of reaction composition comprising a first reaction composition and second reaction composition, both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide.’ Since there is no specific argument for this rejection, as discussed in section 1 regarding this limitation set forth above, with the same reasons as set forth in section 1, the rejection is maintained.

*Id.* at page 6.

As discussed in the Applicants Statement of Interview Summary above, in the previous response, Applicants actually addressed the claim language “determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition. . . .” Since the Examiner agreed to consider Applicants’ argument presented in the previous response, that argument is reiterated below for the convenience of the Examiner.

Applicants assert that the Examiner has failed to establish a *prima facie* case of obviousness. As set forth in the M.P.E.P. at § 2143 at page 2100-129, three basic criteria must be met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success.

Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

As discussed above in connection with claim 26, Wittwer would not have taught or suggested “determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition . . . ,” according to claim 26.

Johnston-Dow would have failed to cure the deficiencies of Wittwer. Specifically, Johnston-Dow would have failed to teach or suggest “determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition . . . ,” according to the method of claim 26.

Each of claims 27, 36-38, 41, and 42 ultimately depend from claim 26, and thus, also comprise “determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition. . . .” Accordingly, for at least that reason, the combination of Wittwer and Johnston-Dow, asserted by the Examiner, would not have taught or suggested all of the elements of claims 27, 36-38, 41, and 42. Applicants, therefore, respectfully assert that the Examiner has not established a *prima facie* case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 27, 36-38, 41, and 42 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wittwer in view of Johnston-Dow.

Because claims 27, 36-38, 41, and 42 would not have been obvious for at least the reasons discussed above, Applicants do not need to address the Examiner's contentions concerning other elements of those claims. By not addressing those contentions, Applicants in no way acquiesce to those contentions.

**IV. Rejection of Claim 46 Under 35 U.S.C. § 103(a)**

The Examiner maintained the rejection of claim 46 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wittwer, as applied to claims 26, 28-35, 39, 40, 43-45, and 47-50, and further in view of U.S. Patent No. 6,790,945 ("Lukhtanov"). Action at page 6, item no. 3. Applicants respectfully traverse that rejection.

The Examiner acknowledged that "Wittwer et al. do not disclose using a minor groove binding molecule as a fluorescent indicator." *Id.* The Examiner alleged that "Lukhtanov et al. disclose oligonucleotide probes containing a minor groove binding molecule. . . ." *Id.* The Examiner further contended that "[o]ne of ordinary skill in the art at the time of the instant invention would have been motivated to apply the minor groove binding molecule of Lukhta[n]ov et al. because Lukhta[n]ov et al. indicate that the reagents used for labeling oligonucleotide overcome the unfavorable characteristics. . . ." *Id.* at pages 6-7. The Examiner also alleged that "[i]t would have been prima facie obvious to have minor groove binding molecule as a fluorescent indicator for determining the presence and sequence of at least one target polynucleotide in a sample." *Id.* at page 7.

The Examiner stated that

[t]he response argues that as discussed above in connection with claim 26, Wittwer would not have taught or suggested the limitation 'combining nucleic acid from the sample with at least one set of reaction composition comprising a first reaction composition and second reaction composition,



both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide.’ Since there is no specific argument for this rejection, as discussed in section 1 regarding this limitation set forth above, with the same reasons as set forth in section 1, the rejection is maintained.

*Id.*

As discussed in the Applicants Statement of Interview Summary above, in the previous response, Applicants actually addressed the claim language “determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition. . . .” Since the Examiner agreed to consider Applicants’ argument presented in the previous response, that argument is reiterated below for the convenience of the Examiner.

As discussed above in connection with claim 26, Wittwer would not have taught or suggested “determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition . . . ,” according to claim 26.

Lukhtanov would have failed to cure the deficiencies of Wittwer. Specifically, Lukhtanov would have failed to teach or suggest “determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition . . . ,” according to the method of claim 26.

Claim 46 ultimately depends from claim 26, and thus, also comprises "determining whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition. . . ." Therefore, for at least that reason, the combination of Wittwer and Lukhtanov, asserted by the Examiner, would not have taught or suggested all of the elements of claim 46. Applicants, therefore, respectfully assert that the Examiner has not established a *prima facie* case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 46 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wittwer in view of Lukhtanov.

Because claim 46 would not have been obvious for at least the reasons discussed above, Applicants do not need to address the Examiner's contentions concerning other elements of that claim. By not addressing those contentions, Applicants in no way acquiesce to those contentions.

#### **CONCLUSION**


Applicants respectfully request reconsideration of the application and the timely issuance of a Notice of Allowance. In the event that the Examiner does not find the claims allowable, Applicants request that the Examiner contact the undersigned at (650) 849-6749 to set up an interview.

Please grant any extensions of time required to enter this response and charge  
any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: November 14, 2006

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